

Application No. : 09/815,982
Filed : March 22, 2001

IN THE SPECIFICATION

1. Please amend the specification as filed at page 1, lines 5 - 7 as follows:

-- This application is a continuation-in-part of U.S. ~~patent application No. 09/342,549~~ Patent No. 6,471,655 entitled "Method And Apparatus For The Noninvasive Determination Of Arterial Blood Pressure" filed June 29, 1999, and assigned to the Applicant herein. --

2. Please amend the specification as filed at page 1, lines 10 - 15 as follows:

-- This application is related to U.S. ~~patent application No. 09/489,160~~ Patent No. 6,514,211 entitled "Method And Apparatus For The Noninvasive Determination Of Arterial Blood Pressure" filed January 21, 2001, and U.S. patent application No. [] 09/815,982 entitled "Method and Apparatus for Assessing Hemodynamic Parameters within the Circulatory System of a Living Subject" filed contemporaneously herewith, both assigned to the Assignee hereof. --

3. Please amend the specification as filed at page 11, lines 12 - 28 as follows:

-- In the invention disclosed herein, however, the optimum applanation is found by evaluating one or more other parameters rather than detecting the maximum pulsatile pressure as in the prior art; i.e., in one embodiment, the invention estimates the maximum time-frequency distribution during an applanation sweep. The maximum time-frequency distribution may be indicative of, inter alia, the maximum arterial diameter. As used herein, the term "diameter" includes the actual diameter of a blood vessel measured in a particular dimension or direction and at a particular point in time, as well as any related parameters calculated based on the actual diameter to include, without limitation, mean diameter calculated over a particular time interval, mean diameter as a function of position on the blood vessel, and maximum diastolic diameter (Appendix A). In the maximum time-frequency method of the present invention, it is hypothesized that the optimum applanation occurs at that point in time 201 during the applanation sweep when the external applied pressure has decreased sufficiently so that internal pressure may oppose it, allowing the sagittal arterial diameter to transiently increase to its maximum as a consequence of reactive hyperemia. This phenomenon may occur at the true mean arterial pressure, during which the transmural pressure equals zero, as shown in ~~Figure2~~ Figure 2. --

4. Please amend the specification as filed at page 21, lines 6-16 as follows:

-- Referring now to Figure 7, which incorporates the ultrasonic filtering circuit of Figure 5a, one embodiment of the ultrasonic driver and receiver circuit 616 is now described. As shown in Figure 7, an oscillator ~~620~~ 670 generates a continuous square wave signal, having a fixed frequency of 8 MHz, for coupling to a gate logic circuit 672 and to an RF mixer ~~674~~ 683. The gate logic circuit transmits 8 us bursts of the 8 MHz signal, interrupted by 8 microsecond dead times. An RF shaper circuit 676 converts the resulting series of square wave bursts from the gate logic circuit 672 into corresponding sine wave bursts, for application through a transducer switch 677, to the ultrasonic transducer 604. The transducer switch 677 routes ultrasonic signals for both applanation and transverse positioning. The ultrasonic transducer 604 is thereby conditioned to transmit a succession of 8 MHz bursts of sonic energy into the adjacent wrist tissue.--

5. Please amend the specification as filed at page 23, line 10 – page 24, line 26 as follows:

-- Referring now to Figures 8 and 9, one embodiment of the applanation and transverse positioning device 800 of the invention is illustrated. It is noted herein that Figure 9 represents a cross-sectional view (including functional block diagram) of the blood pressure measurement system of the embodiment of Figure 8, taken along lines 9-9 of Figure 8. The device 800 is adapted to receive a transducer housing element 822 in the lower extensive portion ~~804~~ thereof. The transducer housing element contains the aforementioned pressure and ultrasonic transducers 602, 604 therein, the latter physically being combined into a single transducer element, although other configurations including a tandem ultrasonic/pressure configuration (not shown), or an array of multiple pressure and/or ultrasonic transducers, may be used. The transducers 602, 604 are free to move within the housing 822 in the sagittal direction 831 and the transverse direction 833 with respect to the artery, as driven by the applanation and positioning motors 842, 844. The housing element 822 of the present embodiment contacts the wrist skin circumferentially around the transducers 602, 604 which move with respect to the housing element 822 and the skin, although it will be appreciated that a variety of different configurations and methods may be used. For example, a substantially compliant housing which conforms to the tissue of the subject, yet allows the transducers 602, 604 to move in the desired directions within an aperture therein, may be substituted. When adhered to the wrist using the wrist brace disclosed herein in Figure 10 (or other retaining mechanism), the active surface ~~810~~ of the transducers 602, 604 is in variable contact with the skin of the wrist, and roughly flush with the bottom edge of the housing element 822. The top of the transducers 602, 604 include an electrical connection 837 to the power supply 838 of the applanation and transverse positioning assembly 800, as well as to circuitry for processing the pressure and

ultrasound signals from the transducers. The transducers are also coupled via a mechanical connection 839 to the motors of the applanation and transverse positioning assembly 800, such that the position of the transducers 602, 604 is varied in the sagittal and transverse directions by the applanation and transverse positioning motors 842, 844, respectively. While a ball-and-socket arrangement is illustrated for the mechanical connection 839 between the transducers 602, 604 and the motors, it will be appreciated that a variety of different arrangements (such as an articulated joint or sliding coupling) may be used. Collectively, the housing element 822 and the applanation and transverse positioning assembly 800 comprise a coupling device, which maintains the transducers 602, 604 properly coupled to the subject's wrist when mounted in the wrist brace of Figure 10. The transducers 602, 604 move in the sagittal direction 831 within the housing element 822 as urged by the applanation motor 842 so as to compress the radial artery to varying degrees during blood pressure measurement. The transverse positioning motor 844 moves the transducers in the transverse direction 833 within the housing element 822 during transverse positioning (described below). In the present embodiment, the applanation motor is controlled by a fuzzy logic control circuit 847 of the type well known in the art so as to perform applanation sweeps, which vary the degree of arterial compression, although other control schemes may be used. For example, the applanation of the artery may be performed so as to maintain the transmural pressure at or near zero. Alternatively, the applanation motor may be modulated by the control circuit in a periodic or continuous fashion such that the artery is compressed according to a desired profile, such as a sinusoid. Such control and modulation schemes are described in Applicant's two co-pending U.S. Patent applications U.S. Patents, numbered 09/120,069 6,228,034 and 09/120,205 6,176,831, both entitled "Apparatus and Method for Non-Invasively Monitoring a Subject's Arterial Blood Pressure" and filed July 20, 1998, which are incorporated herein by reference in their entirety. --

6. Please amend the specification as filed at page 30, line 18 – page 31, line 19 as follows:

-- Figure 16 illustrates one specific embodiment 1600 of the method 1500 of isolating the settling point. In this embodiment, the approximation coefficients of a Haar wavelet transform of scale 6 are calculated in order to enable the essential features of the end-diastolic velocity to be isolated. This transform, $WT(n,6)$, is calculated in step 1602 as set forth in Eqn. 9 below:

$$WT(n,6) = \frac{1}{2^6} \sum_{j=0}^{L-1} x(j) \phi_h \left(\frac{j-h}{2^6} \right), \quad (9)$$

where $x(n)$ is the blood velocity signal, L is the length of the signal (i.e., the total number of samples in the blood velocity signal), and $\phi_h(n)$ is the Haar scaling function as is well known in the mathematical arts. The Haar scaling function is defined as

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$$\phi_h(n) = \begin{cases} 1, & 0 \leq k < 1 \\ \text{otherwise} \end{cases} \quad (10)$$

Note that the length of the wavelet transform is $1/2^6 = 1/64$ the length L of the input signal. Hence, in essence, the transform functions as a low pass filter as illustrated in Figures 14b and 14d. --

- 10 7. Please amend the specification as filed at page 35, line 29 – page 36, line 9 as follows:

-- Accordingly, the present invention advantageously provides such a non-invasive technique (and apparatus) for both locating the blood vessel of interest, and maintaining one or more selected apparatus in a predetermined relationship thereto. Specifically, in one exemplary application, backscattered acoustic energy is analyzed to initially locate the blood vessel which is embedded within the surrounding tissue of the subject. In another application, the backscattered energy is used to maintain a sensing or treatment apparatus (e.g., the pressure and/ultrasonic transducers assembly 800 of the NIBP device previously described herein, or that described in Assignee's ~~co-pending U.S. patent application Serial No. []~~ Patent No. 7,048,691 entitled "Method and Apparatus for Assessing Hemodynamic Parameters Within the Circulatory System of a Living Subject" filed ~~contemporaneously herewith~~ March 22, 2001, and incorporated by reference herein in its entirety) in optimal position with respect to the blood vessel. --

8. Please amend the specification as filed at page 40, lines 19 – 31 as follows:

-- Quadrature demodulation as used in the present embodiment generally comprises multiplication of the A-mode signal by the sine and cosine functions, and lowpass filtering. The purpose of quadrature demodulation is to baseband the A-mode signal, through the removal of the transmit carrier frequency. This method is generally illustrated in Fig. 23. As shown in Fig. 23, quadrature demodulation consists receiving the backscattered "raw" A-mode signal (step. 2302) then multiplying ~~of multiplication of~~ the received backscattered "raw" A-mode signal by the complex exponential, $\exp(-2\pi f_c t)$ where f_c denotes the transmit center frequency of the signal (step 2304). This produces a series of values representing sum and difference frequencies of the complex exponential function and raw A-mode signal. Next, the resulting signal is lowpass filtered (step 2306) to retain only the difference (baseband) frequency components. Since

the exponential function is complex, both an in-phase and quadrature channel are produced, designated I and Q, respectively. This process is also graphically depicted in Fig. 24. --

9. Please amend the specification as filed at page 53, lines 4 – 19 as follows:

-- Accordingly, a simple search algorithm may be used in conjunction with the signal level (envelope-squared) methodology to identify the locations associated with the front and back arterial walls when the A-mode data is of "reasonable" quality. Specifically, as shown in Fig. 32b, the method 3250 comprises first comparing the A-mode signal level to the signal level of the lumen in both (i) the direction toward the transducer, and (ii) in the direction away from the transducer, starting at the depth where the lumen signal was detected (step 3252). The signal level is measured in the selected direction (step 3254); when the signal level is found to meet one or more predetermined criteria (e.g., the signal level of (i) or (ii) above being "n" times as great as the signal level associated with the lumen), the signal is assumed to correspond to the arterial wall (step 3256). The point along the A-mode line towards the transducer at which this criterion is met is denoted as the location of the front arterial wall, and similarly, the point along the A-mode line away from the transducer at which this criterion is met is denoted as the location of the back arterial wall. This is graphically depicted in Fig. 33, which illustrates the relationship between the average power calculation 3302 and the front and back wall artifacts 3304, 3306 present in the A-mode envelope 3308.--

10. Please amend the specification as filed at page 57, lines 11 – 19 as follows:

-- As shown in Fig. 35, the method 3500 generally comprises deriving "raw" wall diameter information which varies as a function of time (step 3502), as previously discussed herein. Next, in step 3504, the wall diameter information of step 3502 is integrated over a pre-selected finite time interval to "smooth" the raw data and eliminate most or all artifact relating to respiration and cardiac cycle. This produces a wall diameter metric (step 3506) which varies as a function of time. The wall diameter metric is then used to generate an error signal (step 3508) which is functionally related to the value of the absolute metric. This error signal is then fed to the aforementioned controller device which varies the lateral position of the transducer element (step 3510) so as to effectively maintain the magnitude of the error signal as small as possible (or alternatively, the value of the wall diameter metric as large as possible) --